K123903

MAY 1 3 2013

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Paul Swift, RAC
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DATE PREPARED: April 25, 2013

DEVICE TRADE NAME: BD BACTEC Lytic/10 Anaerobic/F (plastic)

DEVICE COMMON NAME: Anaerobic blood culture medium

DEVICE CLASSIFICATION: 21 CFR§866.2560, Class I

PREDICATE DEVICE: BD BACTEC Lytic/10 Anaerobic/F medium (K954925)

INTENDED USE:
BD BACTEC™ Lytic/10 Anaerobic/F culture vials (prereduced enriched Soybean-Casein Digest broth with CO_2) are for anaerobic blood cultures. Principal use is with the BACTEC fluorescent series instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.

DEVICE DESCRIPTION:
The sample to be tested is inoculated into one or more vials which are inserted into the BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO_2 produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO_2 present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

DEVICE COMPARISON:
The BD BACTEC Lytic/10 Anaerobic/F (plastic) medium differs from the BD BACTEC Lytic/10 Anaerobic/F (glass) medium in the following ways:

- The medium in the new device is contained in a plastic bottle; whereas, the medium in the predicate device is contained in a glass bottle.
- The new device's sensor has been adjusted to obtain equivalent performance to that of the predicate device
- The new bottle weighs less than the predicate device.
- The new device measures 5.0 inches high compared to the predicate device height of 5.6 inches.

The BD BACTEC Lytic/10 Anaerobic/F (plastic) medium is similar to the BD BACTEC Lytic/10 Anaerobic/F (glass) medium in the following ways:

- Both the new and predicate devices are used for the qualitative anaerobic culture and recovery of microorganisms from human blood.
- Both devices are intended to be used with the BD BACTEC fluorescent-series of blood culture instruments.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same incubation and agitation parameters to both devices.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same growth and detection algorithms to both devices.
- Both devices are incubated at 35° C (± 1.5° C) for a period of up to 120 hours.
- Both devices incorporate a sensor that detects increases in CO_2 within the bottle as a result of organism growth.
- Both devices require a sample volume of 3 – 10 mL of blood.
- Both devices utilize 40 mL of enriched soybean casein digest broth as the growth medium.
- Both devices have a maximum blood to broth ratio of 1:5.

SUMMARY OF PERFORMANCE DATA

Analytical Studies:

Instrument Time to Detection (TTD)
The data included 342 paired sets at the 10-100 CFU per bottle inoculum level and were evaluated in both the new and the predicate devices with 100% recovery. The observed median TTD difference between the paired sets was 10 minutes faster for the BD BACTEC Lytic/10 Anaerobic/F medium contained in a plastic vial. Ninety-five percent of the TTD differences between the paired sets were between -1.68 hours faster for the glass vial and 3 hours faster for the plastic vial.

There were 191 paired sets at the 0-1 and 1-10 CFU per bottle inoculum levels that were positive in both the new and predicate devices.

Percent Recovery
A total of 342 paired sets were evaluated at the 10-100 CFU per bottle inoculum level in the Percent Recovery comparison. All 342 paired sets were positive in both the new and predicate devices (100%). The analysis at the 10-100 CFU per bottle inoculum level supports substantial equivalence.

A subset of organisms, including *Finegoldia magna* (formerly *Peptostreptococcus magnus*) *and Peptoniphilus asaccharolyticus* (formerly *Peptostreptococcus asaccharolyticus)* were evaluated on the BD BACTEC FX instrument at 10 to 100 CFU per vial and demonstrated 100% recovery in both the BD BACTEC Lytic/10 Anaerobic/F medium contained in a plastic vial and the BD BACTEC Lytic/10 Anaerobic/F medium contained in a glass vial.

False Positive Rate
A total of 240 paired sets were used to execute this study. The 240 paired sets were comprised of 80 bottles from each of 3 lots. The paired sets were inoculated with fresh human blood at varying levels (2, 4, 6, 8, 10 mL) and entered into the BACTEC blood culture instrument. It was expected that each bottle would be instrument-negative following the complete protocol (120 hours). There were no false positive bottles of the new device observed during this evaluation.

False Negative Rate
A total of 121 paired sets were evaluated for the determination of the False Negative Rate of the new device. Bottles that were instrument negative at 120 hours but terminal subculture positive would be classified as false negative. Instrument negative bottles were terminally subcultured onto an appropriate medium and incubated under appropriate environmental conditions for up to five days. There were no false negative results with either the new or predicate device under this classification.

Twenty-seven bottles did not detect in the new device only at the 0 to 1 CFU per bottle inoculum level and two bottles did not detect at the 1 to 10 CFU per bottle inoculum level. One of twelve replicates of *Porphyromonas asaccharolytica* (ATCC 25260, 4 CFU per bottle) failed to detect in the BD BACTEC Lytic/10 Anaerobic/F medium contained in a plastic vial. Instrument signal analysis demonstrated no evidence of growth in the replicate and a terminal subculture yielded no growth; indicating that there were likely no viable organisms inoculated into the vial.

Forty-four bottles did not detect in the predicate device only at the 0 to 1 CFU per bottle inoculum level and four bottles did not detect at the 1 to 10 CFU per bottle inoculum level.

BACTEC Instrument Compatibility
A total of 114 paired sets (new and predicate devices) were tested in each the BACTEC FX, BACTEC 9240 and BACTEC 9050 fluorescent-series blood culture instruments at the 10 to 100 CFU per bottle inoculum level. A recovery comparison of the new device versus the predicate device demonstrated that all 114 paired sets were positive in both the new and the predicate devices in each of the BACTEC fluorescent series blood culture instruments.

Comparison Across Lots
In the Percent Recovery study, the new device was evaluated across lots. Three hundred forty two paired sets (114 paired sets x 3 lots) at the 10 to 100 CFU per vial inoculum level yielded 100% (95% CI: 98.9%, 100%) recovery. Recovery was compared between three pairs of lots. Recovery agreed 100% (95% CI: 96.8%, 100%) of the time between any two lots in each sampling of the 114 paired sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Becton, Dickinson and Company
c/o Paul Swift
7 Loveton Circle
Sparks, MD. 21152

May 13, 2013

Re: k123903
Trade/Device Name: BD BACTEC Lytic/10 Anaerobic/F (plastic)
Regulation Number: 21 CFR §866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: I
Product Code: MDB
Dated: April 25, 2013
Received: April 26, 2013

Dear Mr. Swift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known):

Device Name: BD BACTEC Lytic/10 Anaerobic/F Blood Culture Medium (plastic)

Indication For Use:

BD BACTEC™ Lytic/10 Anaerobic/F culture vials (prereduced enriched Soybean-Casein Digest broth with CO_2) are for anaerobic blood cultures. Principal use is with the BACTEC fluorescent series instruments for the qualitative culture and recovery of anaerobic microorganisms from blood.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Raquel A. Peat -S
2013.05.10 14:21:59 -04'00'

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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